

Applicants: Patrick Soon-Shiong et al.
Application No. 10/029,582

PATENT
Atty. Dkt. No. VIVOR1420-1
(073799-1107)

REMARKS

The present invention is directed to microcapsules for the encapsulation of biologically active materials. Invention microcapsules are composed of at least one biocompatible gellable material which has a core containing at least one cell aggregate therein and is not ionically crosslinked; and an outer layer which is covalently crosslinked, or both covalently crosslinked and polyionically crosslinked, but is not ionically crosslinked. These capsules permit enhanced migration and aggregation of the biologically active material within the capsule and enhanced control over the release rates of the biologically active material, while decreasing the risk of biominerilization due to ions required for ionic crosslinking and enabling the biologically active material contained within the capsule to retain a significant proportion of the functionality of the unencapsulated biologically active material.

By the present communication, claim 53 has been amended to define Applicants' invention with greater particularity. No new matter has been introduced by the subject amendments as the amended claim language is fully supported by the specification and original claims. The amendments provided herewith are submitted to place this application in condition for allowance, or at a minimum, in better condition for appeal. Accordingly, entry of the proposed amendments is respectfully requested.

Claims 1-6 and 39-64 remain pending in this application with only claim 53 presently under active prosecution. The status of all claims is presented in the Listing of Claims, beginning at page 2 of this communication.

The rejection of claim 53 under 35 U.S.C. §103(a) as allegedly being obvious over Dionne et al (U.S. Patent No. 5,874,099) is respectfully traversed. Applicant's invention, as defined by claim 53, distinguishes over Dionne et al by requiring a microcapsule which contains:

at least one cell aggregate inside a core (which is not ionically crosslinked); and

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an outer layer (which is covalently crosslinked, or both covalently crosslinked and polyionically crosslinked, but not ionically crosslinked).

Dionne et al does not teach or suggest such a microcapsule. The reference does not teach or suggest that both the core and the outer layer not be ionically crosslinked, as required by instant claim 53. Nor does the reference teach or suggest that the outer layer of the microcapsule be covalently crosslinked, or both covalently crosslinked and polyionically crosslinked, but not ionically crosslinked.

The discussion in the reference which the Examiner has cited (e.g., col. 15, lines 27-38) relates to ionic crosslinking (which is what occurs when an alginate is crosslinked with a multivalent ion such as calcium). Only the present invention contemplates a microcapsule with a core (which is not ionically crosslinked); and an outer layer (which is covalently crosslinked, or both covalently crosslinked and polyionically crosslinked, but not ionically crosslinked).

Moreover, the reference does not provide any motivation to modify the vehicle taught therein to arrive at the instantly claimed microcapsule. Absent a teaching or suggestion in the reference, one of skill in the art would not have been motivated to modify the teachings of the reference to arrive at the instantly claimed microcapsule.

It is respectfully submitted that a *prima facie* case of obviousness has not been established because the reference does not teach or suggest, nor does it provide any motivation to attempt the modifications proposed by the Examiner. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

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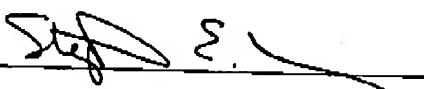
PATENT
Atty. Dkt. No. VIVOR1420-1
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In view of the foregoing amendments and remarks, it is respectfully submitted that the pending claim is in condition for allowance. An early notice to that effect is earnestly solicited. Should any matters remain outstanding, the Examiner is encouraged to contact the undersigned at the telephone number listed below so that a prompt disposition of this application can be achieved.

Respectfully submitted,

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